REMARKS

In Item 18 on page 2 of the Office Action, claims 25-34 are rejected under the judicially-created doctrine of obviousness-type double patenting over U.S. Pat. No. 5,356,810.

The rejection is improper.

The instant application has an effective filing date of 8 August 1988 whereas U.S. Pat. No. 5,356,810 has an effective filing date of 12 November 1989, subsequent to the effective filing date of the instant application. Thus, it is not possible to rely on the later filed but earlier issued patent as a basis for the rejection. See for example, In re Braat, 19 USPQ2d 1289 (Fed. Cir. 1991).

Thus, withdrawal of the rejection is required.

In Items 19 and 20 on pages 3 and 4 of the Office Action, the specification is objected to and claims 25-34 are rejected under 35 USC § 112, first paragraph.

The Examiner takes the position that additional strains are required to practice the invention as claimed. The Examiner acknowledges that the statute can be satisfied by a repeatable method set forth in the specification.

The objection and rejection are traversed for the following reasons.

The instant specification teaches in great detail a repeatable method for obtaining Phaffia rhodozyma mutants with an astaxanthin content higher than found in naturally occurring Phaffia rhodozyma. The instant specification teaches that the starting material may be a wild-type strain or may be a mutant strain already producing high levels of astaxanthin than found in a wild-type strain.

The starting materials are publicly available, the mutagens are publicly available, the screening method set forth in the instant specification can be mere visual inspection of the colonies but can involve known methods for determining actual amounts of astaxanthin and the specification provides, and the record supplements, a reproducible method for obtaining astaxanthin mutants without undue experimentation.

Wild-type strains and two Phaffia rhodozyma strains expressing higher levels of astaxanthin than found in wild-type strains are on deposit at the ATCC and are freely available to the public.

The specification teaches a variety of agents within the scope of the instant invention that can be used to obtain mutant yeast expressing higher levels of astaxanthin. The mutagens are available to the artisan and the method provided in the instant specification is patented, attesting to the enablement of the instant application.

Hence, the issue cannot be for want of available starting materials.

As noted at pages 15 et seq., various strains producing enhanced levels of astaxanthin were produced, see Figure 2, the accompanying text in the instant specification and the working examples.

Appended to the amendment filed 16 December 1993 in parent case U.S. Ser. No. 067,797, is a copy of a Declaration under 37 CFR 1.132 providing additional data demonstrating the reproducibility of the instant invention.

Clearly, applicants have demonstrated the reproducibility of the patented method and demonstrated that undue experimentation is not required to obtain an astaxanthin mutant within the scope of the claims.

If necessary, and at great hardship, applicants will provide a Rule 132 Declaration to substantiate the enablement of the instant invention, but certainly applicants believe such a filing is not required in view of the very thorough teaching of how to make and how to use the instant invention.

The law holds that an assertion by the Patent Office that the enabling disclosure of the instant invention is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Bowen*,

181 USPQ 48 (CCPA 1974); *In re Arnbruster*, 185 USPQ 152 (CCPA 1975). It is not seen how the patented method of the instant invention can be considered legally insufficient to support the products of that patented method.

As stated repeatedly in the record, the instant invention teaches in clear and distinct terms a reproducible method for making Phaffia with enhanced astaxanthin content. A plurality of examples obtained by the method taught in the instant specification are set forth in the instant specification.

There is no evidence of record to doubt the reproducibility of the method disclosed in the instant application nor is there any legally or technically tenable reasoning to demonstrate that the instant invention is not reproducible. Numerous examples of yeast of enhanced astaxanthin content are documented in the record.

Clearly, the instant specification objectively and sufficiently teaches a repeatable method for making and for using the invention as claimed. Hence the instant specification is in full compliance with 35 USC § 112. There is no evidence of record to establish a prima facie case of non-enablement and to maintain such an unsupported position is highly prejudicial to the real party of interest, a small American biotechnology company.

Withdrawal of the objection and rejection is necessary and requested respectfully.

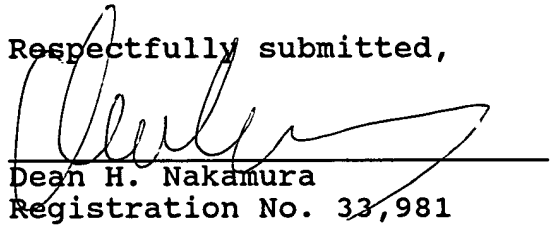
CONCLUSION

The instant application is in condition for allowance. Reexamination, withdrawal of the improper objection and rejections and early notification of allowance are requested respectfully.

Applicants hereby petition for any extension of time which may be required to maintain the pendency of instant case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

If any issues remain outstanding, the Examiner is urged to contact the undersigned at the local exchange indicated hereinbelow so that a hasty resolution and allowance can be obtained without further delay.

Respectfully submitted,



Dean H. Nakamura
Registration No. 33,981

SUGHRUE, MION, ZINN,
MACPEAK & SEAS
2100 Pennsylvania Avenue, N.W.
Washington, D.C. 20037-3202
(202) 293-7060
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